



UNITED STATES DEPARTMENT OF COMMERCE
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SERIAL NUMBER	FLING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
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08/483,728 06/07/95 JAIN

K RO60210.1-ND

EXAMINER

NAFF, D

18M1/0905

FELFE & LYNCH
805 THIRD AVENUE
NEW YORK NY 10022

ART UNIT	PAPER NUMBER
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1808

DATE MAILED:

09/05/95

This is a communication from the examiner in charge of your application.
COMMISSIONER OF PATENTS AND TRADEMARKS

☒ This application has been examined ☐ Responsive to communication filed on _____ ☐ This action is made final.

A shortened statutory period for response to this action is set to expire 3 month(s), _____ days from the date of this letter.
Failure to respond within the period for response will cause the application to become abandoned. 35 U.S.C. 133

Part I THE FOLLOWING ATTACHMENT(S) ARE PART OF THIS ACTION:

- | | |
|--|--|
| 1. <input checked="" type="checkbox"/> Notice of References Cited by Examiner, PTO-892. | 2. <input checked="" type="checkbox"/> Notice of Draftsman's Patent Drawing Review, PTO-948. |
| 3. <input type="checkbox"/> Notice of Art Cited by Applicant, PTO-1449. | 4. <input type="checkbox"/> Notice of Informal Patent Application, PTO-152. |
| 5. <input checked="" type="checkbox"/> Information on How to Effect Drawing Changes, PTO-1474. | 6. <input type="checkbox"/> _____ |

Part II SUMMARY OF ACTION

1. ☒ Claims 1-50 are pending in the application.
Of the above, claims _____ are withdrawn from consideration.
2. ☐ Claims _____ have been cancelled.
3. ☐ Claims _____ are allowed.
4. ☒ Claims 1-50 are rejected.
5. ☐ Claims _____ are objected to.
6. ☐ Claims _____ are subject to restriction or election requirement.
7. ☐ This application has been filed with informal drawings under 37 C.F.R. 1.85 which are acceptable for examination purposes.
8. ☐ Formal drawings are required in response to this Office action.
9. ☐ The corrected or substitute drawings have been received on _____. Under 37 C.F.R. 1.84 these drawings are ☐ acceptable; ☐ not acceptable (see explanation or Notice of Draftsman's Patent Drawing Review, PTO-948).
10. ☐ The proposed additional or substitute sheet(s) of drawings, filed on _____, has (have) been ☐ approved by the examiner; ☐ disapproved by the examiner (see explanation).
11. ☐ The proposed drawing correction, filed _____, has been ☐ approved; ☐ disapproved (see explanation).
12. ☐ Acknowledgement is made of the claim for priority under 35 U.S.C. 119. The certified copy has ☐ been received ☐ not been received ☐ been filed in parent application, serial no. _____; filed on _____.
13. ☐ Since this application appears to be in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under Ex parte Quayle, 1935 C.D. 11; 453 O.G. 213.
14. ☐ Other

EXAMINER'S ACTION

The Group and/or Art Unit location of your application in the PTO has changed. To aid in correlating any papers for this application, all further correspondence regarding this application should be directed to Group Art Unit 1808.

5 This application is a continuation of application Serial No. 08/181,269.

Claims in the case are 1-50.

The following is a quotation of the first paragraph of 35 U.S.C. § 112:

10 The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to
15 enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

The specification is objected to under 35 U.S.C. § 112, first paragraph, as failing to provide an enabling disclosure.

20 The specification fails to describe how to make a gelfoam as required by claims such as 8. While a gelfoam is described as a gelatin sponge at page 13, line 10, there is no description of how the gelatin sponge is made.

25 Claims 8-14, 27-31 and 46 are rejected under 35 U.S.C. § 112, first paragraph, for the reasons set forth in the objection to the specification.

Claims 1, 3-8, 10-15 and 17-50 are rejected under 35 U.S.C. § 112, first paragraph, as the disclosure is enabling only for claims limited to coating with agarose as required by claim 2, 9 or 16 with respect to the independent claim each claim depends

on. The working examples in the specification use only the method of claim 2, 9 or 16 for coating and no other method has been disclosed. It would be uncertain as to whether the disclosed results would be obtained when other methods of coating are used.

In regard to claims 22-50, the disclosure is enabling for only a macrobead prepared as required by claim 1, 8 or 15 when requiring a coating method as set forth above. It would be uncertain as to results to expect when other methods are used to produce the macrobeads.

In regard to claims 37-47, the specification is enabling for only mice as the patient. Clinical tests with mice do not enable treating other animals and humans unless it is recognized in the art that results from a specific treatment of mice will be obtained when the treatment is applied to other animals and humans. See M.P.E.P. §§ 706.03(n) and 706.03(z).

Claims 1-50 are rejected under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The claims are confusing and unclear by reciting "macrobead". The meaning and scope of this term is uncertain since the size of a bead that is "macro" is relative and subjective.

In claim 2 and other claims that recite "contacting-----to mineral oil", "to" should be changed to -- with -- to be clearer.

Further see claims 9 and 16.

In step (a) of claim 8, it is uncertain as to the meaning of "suspending secretory cells on gelfoam". How can cells be suspended on a solid material?

5 Claims 29-31 and 34-36 are confusing in reciting "agarose-collagen" since there is no antecedent basis for this term in the claims on which they depend.

10 In line 1 of claim 8 and where recited in other claims, it is uncertain as to material that is a "gelfoam". The specification fails to describe in detail the structure of a gelfoam and how it is made.

The following is a quotation of 35 U.S.C. § 103 which forms the basis for all obviousness rejections set forth in this Office action:

15 A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that
20 the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

25 Subject matter developed by another person, which qualifies as prior art only under subsection (f) or (g) of section 102 of this title, shall not preclude patentability under this section where the subject matter and the claimed invention were, at the time the invention was made, owned by the same person or subject to an obligation of assignment to the same
30 person.

35 This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. § 103, the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 C.F.R. § 1.56 to point out the inventor and invention dates of each claim that was not

commonly owned at the time a later invention was made in order for the examiner to consider the applicability of potential 35 U.S.C. § 102(f) or (g) prior art under 35 U.S.C. § 103.

Claims 15-21, 32-36, 37-44 and 47-50 are rejected under 35 U.S.C. § 103 as being unpatentable over Cook et al in view of Tsang et al or Larsson et al and Goosen et al.

The claims are drawn to preparing an agarose coated, agarose secretory cell macrobead and its use to treat a patient and to preserve secretory cells.

Cook et al disclose forming agarose beads (paragraph bridging cols 3 and 4) that can contain animal cells (paragraph bridging cols 10 and 11).

Tsang et al disclose post-coating of alginate beads containing cells with alginate to prevent clumping (col 6, lines 23-35).

Larsson et al disclose coating solid particles with agarose (examples 1-5) to provide the particles with an active layer.

Goosen et al disclose alginate beads containing secretory cells post-coated with alginate (col 8, lines 25-30).

It would have been obvious to post-coat the agarose beads of Cook et al with agarose as suggested by the Tsang et al and Goosen et al post-coating alginate beads with alginate and Larsson et al coating particles with agarose to provide an active layer since it would have been expected that agarose coated on the agarose beads would prevent clumping as disclosed by Tsang et al and provide an active layer as disclosed by Larsson et al. It

would have been obvious from Goosen et al to select secretory cells as the animal cells of Cook et al when the function of these cells is needed and implant beads containing the cells as suggested by Goosen et al. Preserving as in claims 48-50 would have been inherent when forming beads as suggested by the references as set forth above.

Claims 1-7, 22-26, 37-45 and 48-50 are rejected under 35 U.S.C. § 103 as being unpatentable over the references as applied to claims 15-21, 32-36, 37-44, and 47-50 above, and further in view of Mosbach et al and Brodelius et al.

The claims are drawn to agarose coated beads and their use as set forth above except that the beads contain agarose-collagen.

It would have been obvious to mix collagen with the agarose of Cook et al in view of Mosbach et al disclosing that collagen or agarose can be used to make beads containing cells (examples 1 and 9) and Brodelius et al disclosing entrapping cells in beads of a copolymer of gelatin (comes from collagen) and agarose (page 313, left col, 4th paragraph). Combining two well known bead forming materials to obtain their properties in combination would have been obvious.

Claims 8-14, 27-31, 37-44, 46 and 48-50 rejected under 35 U.S.C. § 103 as being unpatentable over Tice et al in view of Tsang et al or Larsson et al and Goosen et al.

The claims are drawn to agarose coated beads and their use as set forth above except that the beads are made of gelfoam.

Tice et al discloses porous protein beads such as porous gelatin(col 3, line 59) beads containing animal cells for implanting.

It would have been obvious in view of the secondary references for reasons set forth above to coat the beads of Tice et al with agarose. The beads of Tice et al are made porous with a pore forming compound(col 6, lines 40-65) and to alternatively make the beads porous by forming a foam would have been a matter of obvious choice.

The following is a quotation of the appropriate paragraphs of 35 U.S.C. § 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless --

(e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

(f) he did not himself invent the subject matter sought to be patented.

Claims 1-50 are provisionally rejected under 35 U.S.C. 102(e) as being anticipated by copending application Serial No. 08/181,269 which has a common inventor with the instant application.

Based upon the earlier effective U.S. filing date of the copending application, it would constitute prior art under 35 U.S.C. 102(e) if patented. This provisional rejection under 35 U.S.C. 102(e) is based upon a presumption of future patenting of the copending application. This application is a continuation of

parent application Serial No. 08/181,269 and discloses the same invention. Serial No. 08/181,269 is a reference since it has a different inventive entity, i. e. it contains Smith as an inventor who is not listed on the present application as an inventor. Since the inventive entities are different and the invention in both applications is the same, the filing date of the parent application cannot be relied on as an effective filing date of the present application since the inventors of the present application are not the inventors of the invention in the parent application. A change of inventorship in the present application under 37 C.F.R. § 1.48a as in the parent application would obviate this rejection.

Also, this provisional rejection under Section 102(e) might be overcome either by a showing under 37 CFR 1.132 that any invention disclosed but not claimed in the copending application was derived from the inventor of this application and is thus not the invention "by another," or by an appropriate showing under 37 CFR 1.131.

Claims 1-50 are rejected under 35 U.S.C. § 102(f) because the applicant did not invent the claimed subject matter.

Since the parent application discloses the same invention as presently claimed and has a different inventive entity as set forth above, the inventors listed on the present application are not the inventors of the presently claimed invention. A change of inventorship as set forth above would obviate this rejection.

Claims 1-50 are provisionally rejected under the judicially

created doctrine of obviousness-type double patenting as being unpatentable over claims 51-55 and 58-69 of copending application Serial No. 08/181,269. Although the conflicting claims are not identical, they are not patentably distinct from each other because the present claims are directed to variations in the claimed invention of the copending application that would have been matters of obvious choice depending in individual preference and convenience within the skill of the art.

This is a *provisional* obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

The non-statutory double patenting rejection, whether of the obvious-type or non-obvious-type, is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent. *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); *In re Van Ornam*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); and *In re Goodman*, 29 USPQ2d 2010 (Fed. Cir. 1993).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321 (b) and (c) may be used to overcome an actual or provisional rejection based on a non-statutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.78 (d).

Effective January 1, 1994, a registered attorney or agent of record may sign a Terminal Disclaimer. A Terminal Disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to David M. Naff whose telephone number is (703) 308-0520. The examiner can normally be reached on Monday-Thursday and every other Friday

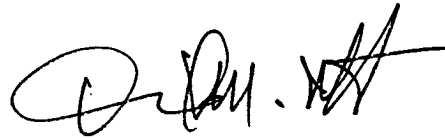
from about 8:30 AM to about 6:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, a message can be left on voice mail. The fax phone number is (703) 308-0294.

5 Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-0196.

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DMN
September 1, 1995



DAVID L. NAFF
PRIMARY EXAMINER
ART UNIT 1808